

A35008-PCT-USA-A (070050.2429) PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Modak et al.

Costumer No.:

21003

Serial No.

10/622,272

Examiner:

Not Yet Assigned

Filed

July 17, 2003

Group Art Unit:

Not Yet Assigned

For

ZINC SALT COMPOSITIONS FOR THE PREVENTION OF DERMAL

AND MUCOSAL IRRITATION

INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

November 3, 2004

Date of Deposit

Lisa B. Kole

35,255

Patent Reg. No.

Attorney Narh

November 3, 2004

Date of Signature

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents listed below in reverse chronological order and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Copies of the documents listed are enclosed.

Several of the listed patent documents have been cited on the International Search Report for International Patent Application No. PCT/US03/03896, to which the present application claims priority. A copy of the International Search Report is also enclosed, which indicates the possible relevance of each document cited therein.

- U.S. Patent Application Publication No. US2003/0152644 to Modak et al., published August 14, 2003;
- 2. International Patent Publication No. WO 03/034994, published May 1, 2003;
- 3. Cimiotti JP, Marmur ES, Nesin M, Hamlin-Cook P, Larson EL. Adverse reactions associated with an alcohol-based hand antiseptic among nurses in a neonatal intensive care unit. Am. J. Infect. Control 2003;131:43-48;
- 4. U.S. Patent No. 6,426,062 to Chopra et al., issued July 30, 2002;
- 5. U.S. Patent No. 6,387,357 to Chopra et al., issued May 14, 2002;
- 6. U.S. Patent No. 6,352,701 to Scholz et al., issued March 5, 2002;
- 7. Bleasel N, Tate B, Rademaker M. Allergic contact dermatitis following exposure to essential oils. *Australian Journal of Dermatology* 2002; 43: 211-213;
- 8. Vilaplana J, Romaguera C. Contact dermatitis from the essential oil of tangerine in fragrances. *Contact Dermatitis* 2002;46:108;
- 9. U.S. Patent No. 6,204,230 to Taylor et al., issued March 20, 2001;
- 10. U.S. Patent No. 6,187,327 to Stack, issued February 13, 2001;
- 11. Nair B. Final report on the safety assessment of Mentha Piperita (Peppermint) oil, Mentha Piperita (Peppermint) Leaf extract, Mentha Piperita (Peppermint) leaf and Mentha Piperita (Peppermint) water. *International Journal of Toxicology* 2001;20(Suppl

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- 3):61-73;
- 12. Larsen W, Nakayama H, Fischer T, Elsner P, Frosch P, Burrows D, Jordan W, Shaw S, Wilkinson J, Marks J Jr, Sugawara M, Nethercott M, Nethercott J. Fragrance contact dermatitis: a worldwide multicenter investigation (Part II). Contact Dermatitis 2001;44:344-346;
- 13. Wöohrl S, Hemmer W, Focke M, Gotz M, Jarisch R. The significance of fragrance mix, balsam of Peru, colophony and propolis as screening tools in the detection of fragrance allergy. *British Journal of Dermatology* 2001;145(2):268-273;
- 14. U.S. Patent No. 6,136,771 to Taylor et al., issued October 24, 2000;
- 15. U.S. Patent No. 6,107,261 to Taylor et al., issued August 22, 2000;
- 16. U.S. Patent No. 6,037,386 to Modak et al., issued March 14, 2000;
- 17. U.S. Patent No. 6,022,551 to Jampani et al., issued February 8, 2000;
- 18. Sugiura M, Hayakawa R, Kato Y, Sugiura K, Hashimoto R. Results of patch testing with lavender oils in Japan. *Contact Dermatitis* 2000;43:157-160;
- 19. U.S. Patent No. 5,985,918 to Modak et al., issued November 16, 1999;
- 20. U.S. Patent No. 5,980,477 to Kelly, issued November 9, 1999;
- 21. U.S. Patent No. 5,965,610 to Modak et al., issued October 12, 1999;
- 22. U.S. Patent No. 5,951,993 to Scholz et al., issued September 14, 1999;
- 23. U.S. Patent No. 5,885,562 to Lowry et al., issued March 23, 1999;
- 24. U.S. Patent No. 5,776,430 to Osborne et al., issued July 7, 1998;
- 25. U.S. Patent No. 5,708,023 to Modak et al., issued January 13, 1998;
- 26. U.S. Patent No. 5,705,532 to Modak et al., issued January 6, 1998;

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- 27. De Groot A, Frosch PJ. Adverse reactions to fragrances: a clinical review. *Contact Dermatitis* 1997;36:57-86;
- 28. U.S. Patent No. 5,591,442 to Diehl et al., issued January 7, 1997;
- 29. U.S. Patent No. 5,516,510 to Beilfuss et al., issued May 14, 1996;
- 30. U.S. Patent No. 5,403,864 to Bruch et al., issued April 4, 1995;
- 31. U.S. Patent No. 5,357,636 to Dresdner, Jr. et al., issued October 25, 1994;
- 32. European Patent Application No. 0 604 848, published July 6, 1994;
- 33. U.S. Patent No. 5,208,031 to Kelly, issued May 4, 1993;
- 34. U.S. Patent No. 5,133,090 to Modak et al., issued July 28, 1992;
- 35. U.S. Patent No. 5,059,416 to Cherukuri et al., issued October 22, 1991;
- 36. U.S. Patent No. 4,956,170 to Lee, issued September 11, 1990;
- 37. U.S. Patent No. 4,889,844 to Silvetti, Sr. et al., issued December 26, 1989;
- 38. U.S. Patent No. 4,853,978 to Stockum, issued August 8, 1989;
- 39. U.S. Patent No. 4,478,853 to Chaussee, issued October 23, 1984; and
- 40. U.S. Patent No. 3,485,915 to Gerstein et al., issued December 23, 1969.

Identification of the listed documents is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as "prior art" against the subject application. If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

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Applicants further reserve the right to take appropriate action to establish the patentability

of the disclosed invention over the listed documents, should the documents be applied against the

claims of the present application.

Applicants believe there is no fee required for this timely submission. However, if any

fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to

charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate

copy of this paper is enclosed.

Respectfully submitted,

BAKER BOTTS L.L.P.

Lisa B. Kolé

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Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office

Atty. Docket No. A35008-PCT-USA-A (070050.2429) Serial No. 10/622,272

PIEFORMATION DISCLOSURE STATEMENT BY APPLICANT Applicants
Modak et al.
Filing Date

July 17, 2003

Group Art Unit Not Yet Assigned

Use several sheets if necessary)

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ILS. PATENT DOCUMENTS

THADEWARE									U.S. PATENT DOCUMENTS				
Exam. Init.			•	Docu	iment l	No.			Date	Name	Class	Subclass	Filing Date ifAppropriate
	4.	6	4	2	6	0	6	2	07/30/02	Chopra et al.	424	65	
 	5.	6	3	8	7	3	5	7	05/14/02	Chopra et al.	424	65	
4	6.	6	3	5	2	7	0	1	03/05/02	Scholz et al.	424	405	
	9.	6	2	0	4	2	3	0	03/20/01	Taylor et al.	510	131	
· ·	10.	6	1	8	7	3	2	7	02/13/01	Stack	424	405	
	14.	6	1	3	6	7	7	1	10/24/00	Taylor et al.	510	388	
	15.	6	1	0	7	2	6	1	08/22/00	Taylor et al.	510	131	
	16.	6	0	3	7	3	8	6	03/14/00	Modak et al.	524	105	
	17.	6	0	2	2	5	5	1	02/08/00	Jampani et al.	424	405	
	19.	5	9	8	5	9	1	8	11/16/99	Modak et al.	514	494	
	20.	5	9	8	0	4	7	7	11/09/99	Kelly	602	77	
	21.	5	9	6	5	6	1	0	10/12/99	Modak et al.	514	494	
	22.	5	9	5	1	9	9	3	09/14/99	Scholz et al.	424	405	
	23.	5	8	8	8	5	6	2	03/23/99	Lowry et al.	424	65	
	24.	5	7	7	6	4	3	0	07/07/98	Osborne et al.	424	43	
 	25.	5	7	0	8	0	2	3	01/13/98	Modak et al.	514	494	
	26.	5	7	0	5	5	3	2	01/06/98	Modak et al.	514	635	
	28.	5	5	9	1	4	4	2	01/07/97	Diehl et al.	424	401	
	29.	5	5	1	6	5	1	0	05/14/96	Beilfuss et al.	424	65	
	30.	5	4	0	3	8	6	4	04/04/95	Bruch et al.	514	721	
	31.	5	3	5	7	6	3	6	10/25/94	Dresdner, Jr. et al.	2	161.7	
	33.	5	2	0	8	0	3	1	05/04/93	Kelly	424	412	
	34.	5	1	3	3	0	9	0	07/28/92	Modak et al.	2	168	

Examiner Date Considered

^{*} Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant. NY02:457646.1

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office										Atty. Docket No. A35008-PCT-USA-A (070050.2429)	L L	Serial No. 10/622,272			
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.	35.	5 0 5 9 4 1 6 10/22/91								Cherukuri et al.	424	48			
	36.	4	9	5	6	1	7	0	09/11/90	Lee	424	81			
	37.	4	8	8	9	8	4	4	12/26/89	Silvetti, Sr. et al.	514	60			
	38.	4	8	5	3	9	7	8	08/08/89	Stockum	2	167			
	39.	4	4	7	8	8	5	3	10/23/84	Chaussee	424	358			
5	40.	3	4	8	5	9	1	5	12/23/69	Gerstein et al.	424	81			
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									`	Author, Title Date, Pertine					
	1.	US Patent Application Publication No. US2003/0152644 to Modak et al., published August 14, 2003.													
	3.	Cimiotti JP, Marmur ES, Nesin M, Hamlin-Cook P, Larson EL. Adverse reactions associated with an alcohol-based hand antiseptic among nurses in a neonatal intensive care unit. <i>Am. J. Infect. Control</i> 2003:131:43-48.													
•	7.	Bleasel N, Tate B, Rademaker M. Allergic contact dermatitis following exposure to essential oils. Australian Journal of Dermatology 2002;43:211-213.													
	8.	Vilaplana J, Romaguera C. Contact dermatitis from the essential oil of tangerine in fragrances. Contact Dermatitis 2002;46:108.													
	11.	Nair B. Final report on the safety assessment of Mentha Piperita (Peppermint) oil, Mentha Piperita (Peppermint) Leaf extract, Mentha Piperita (Peppermint) leaf and Mentha Piperita (Peppermint) water. <i>International Journal of Toxicology</i> 2001;20(Suppl 3):61-73.													
	12.	Larsen W, Nakayama H, Fischer T, Elsner P, Frosch P, Burrows D, Jordan W, Shaw S, Wilkinson J, Marks J Jr, Sugawara M, Nethercott M, Nethercott J. Fragrance contact dermatitis: a worldwide multicenter investigation (Part II). Contact Dermatitis 2001;44:344-346.													
	13.	Wohrl S, Hemmer W, Focke M, Gotz M, Jarisch R. The significance of fragrance mix, balsam of Peru, colophony and propolis as screening tools in the detection of fragrance allergy. <i>British Journal of Dermatology</i> 2001;145(2):268-273.													
	18.							ato Y 57-16		Iashimoto R. Results of patc	h testing with	lavender oi	ls in Jap	oan.	
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^{*} Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant. NY02:457646.1